UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,726	06/05/2007	Roy Deudutta	21085.0064U2	1414

23859 7590 12/05/2008

Ballard Spahr Andrews & Ingersoll, LLP
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30309-3915

EXAMINER	
GUSSOW, ANNE	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
12/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,726	DEUDUTTA, ROY	
	Examiner	Art Unit	
	ANNE M. GUSSOW	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-63* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence Alignment*.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 2 is a polypeptide comprising an amino acid sequence at least about 95% identical to SEQ ID No. 1. In view of this Drmanac, et al. (US PG PUB 2005/0196754) reads on the claim. Drmanac, et al. teach a polypeptide #14538 which is 93.4% identical to SEQ ID No. 1 (see sequence alignment). The claim recites the phrase "at least about" which is considered to be broad claim language, the 93.4% identical polypeptide reads on the polypeptide which is "at least about 95% identical to SEQ ID No. 1. Therefore the technical feature recited in claim 2 is not special. Accordingly the groups are not so linked at to form a single general concept under rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, drawn to a polypeptide comprising SEQ ID No. 1.

Group II, claim(s) 4-10, drawn to a nucleic acid, vector, and host cell producing SEQ ID No. 1.

Group III, claim(s) 11-13, drawn to a polypeptide comprising SEQ ID No. 2.

Group IV, claim(s) 14-20, drawn to a nucleic acid, vector, and host cell producing SEQ ID No. 2.

Group V, claim(s) 21-23, drawn to a polypeptide comprising SEQ ID No. 8.

Group VI, claim(s) 24-30, drawn to a nucleic acid, vector, and host cell producing SEQ ID No. 8.

Group VII, claim(s) 31-36, drawn to an antibody that binds to SEQ ID No. 8.

Group VIII, claim(s) 37-42, drawn to an antibody that binds to SEQ ID No. 2.

Group IX, claim(s) 43-46, drawn to a method for detecting cancer using PCR.

Group X, claim(s) 47 in part, drawn to a probe comprising nucleotides of SEQ ID No. 3.

Group XI, claim(s) 47 in part, drawn to a probe comprising nucleotides of SEQ ID No. 4.

Group XII, claim(s) 47 in part, drawn to a probe comprising nucleotides of SEQ ID No. 5.

Group XIII, claim(s) 47 in part, drawn to a probe comprising nucleotides of SEQ ID No. 9.

Group XIV, claim(s) 48-51, drawn to a method for detecting cancer using hybridization.

Group XV, claim(s) 52-55, drawn to a method for detecting cancer using an antibody.

Group XVI, claim(s) 56 and 59, drawn to a method of treatment administering an antisense oligonucleotide.

Group XVII, claim(s) 57 and 59, drawn to a method of treatment administering a ribozyme.

Group XVIII, claim(s) 58 and 59, drawn to a method of treatment administering an siRNA.

Group XIX, claim(s) 60 and 61, drawn to a method of identifying a compound by administering a test compound.

Group XX, claim(s) 62 and 63, drawn to a method of identifying a compound by administering a test compound and estrogen.

2. The inventions listed as Groups I-XX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above in view of the teachings of Drmanac, et al., the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 2 is not special. Groups XIV and X are related by product and method of using. Their shared technical feature is a specific probe for detecting cancer. Group I requires a polypeptide of SEQ ID No. 1 which is not required for Groups II-XX. Group II requires a nucleic acid which encodes SEQ ID No. 1 which is not required for Groups I or III-XX. Group III requires a polypeptide of SEQ ID No. 2 which is not required for Groups I, II, or IV-XX. Group IV requires a nucleic acid which encodes SEQ ID No. 2 which is not required for Groups I-III or V-XX. Group V requires a polypeptide of SEQ ID No. 8 which is not required for Groups I-IV or VI-XX. Group VI requires a nucleic acid which encodes SEQ ID No. 8 which is not required for Groups I-V or VII-XX. Group VII requires an antibody that binds to SEQ ID No. 8 which is not required for Groups I-VI or VIII-XX. Group VIII requires an antibody that binds to SEQ ID No. 2 which is not required for Groups I-VII or IX-XX. Group IX requires PCR which is not required for Groups I-VIII or X-XX. Group XI requires SEQ ID No. 4 which is not required for Groups I-X or XII-XX. Group XII requires SEQ ID No. 5 which is not required for Groups I-XI or XIII-XX. Group XIII requires SEQ ID No. 9 which is not required for Groups I-XII or XIV-XX. Group XV requires an antibody which is not required for Groups I-XIV or XVI-XX. Group XVI requires an antisense oligonucleotide which is not required for Groups I-XV or XVII-XX.

Group XVII requires a ribozyme which is not required for Groups I-XVI or XVIII-XX. Group XVIII requires an siRNA molecule which is not required for Groups I-XVII, XIX, or XX. Group XIX requires administering a test compound which is not required for Groups I-XVIII or XX. Group XX requires administering estrogen which is not required for Groups I-XIX.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;
(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
(d) the prior art applicable to one invention would not likely be applicable to another invention;
(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election

shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

December 2, 2008

/David J Blanchard/
Primary Examiner, Art Unit 1643